# Complete Summary

#### **GUIDELINE TITLE**

Diabetic foot disorders: a clinical practice guideline.

## BIBLIOGRAPHIC SOURCE(S)

Frykberg RG, Armstrong DG, Giurini J, Edwards A, Kravette M, Kravitz S, Ross C, Stavosky J, Stuck R, Vanore J. Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Surgeons. J Foot Ankle Surg 2000; 39(5 Suppl): S1-60. [248 references]

# **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** 

## SCOPE

## DISEASE/CONDITION(S)

- Diabetic foot ulcers
- Diabetic foot infections

IDENTIFYING INFORMATION AND AVAILABILITY

Diabetic Charcot foot

## **GUIDELINE CATEGORY**

Diagnosis Evaluation Management Prevention Treatment

# CLINICAL SPECIALTY

Cardiology Endocrinology Family Practice
Infectious Diseases
Internal Medicine
Nephrology
Nursing
Orthopedic Surgery
Podiatry
Surgery

#### INTENDED USERS

Advanced Practice Nurses Nurses Physician Assistants Physicians Podiatrists

## GUIDELINE OBJECTIVE(S)

To present clinical practice guidelines on the diagnosis, treatment, management, and prevention of diabetic foot disorders

#### TARGET POPULATION

Patients with diabetes mellitus who have or who are at risk of developing diabetic foot disorders

## INTERVENTIONS AND PRACTICES CONSIDERED

#### Diagnosis and Evaluation

- 1. History (global history, foot-specific history, wound/ulcer history)
- 2. Clinical examination (vascular, neurologic, musculoskeletal, dermatologic, footwear)
- 3. Classification of patients according to risk category
- 4. Diagnostic procedures:
  - a. Laboratory testing as indicated
  - b. Imaging studies [e.g. x-rays, and other studies as indicated (computed tomography scans, technetium bone scans, gallium 67 citrate, white blood cell scintigraphy, magnetic resonance imaging)]
  - c. Vascular procedures (e.g. noninvasive arterial studies, such as Doppler segmental arterial pressure, transcutaneous oxygen tension, and toe pressures)
  - d. Neurologic procedures (e.g. Semmes-Weinstein monofilament; Biothesiometer; Vibration perception with tuning fork; deep tendon reflexes)
  - e. Plantar foot pressure assessment
- 5. Assessment of diabetic foot ulcers (extremity assessment; ulcer evaluation and classification)

Management/Treatment of Diabetic Foot Ulcers

- 1. Debridement of necrotic tissue (surgical, mechanical autolytic, enzymatic)
- 2. Pressure reduction (crutches, healing sandal, contact cast, walking brace, foot cast, felt aperture padding, etc.)
- 3. Wound care (topical saline gauze dressings, antiseptics, special dressings, growth factors, bioengineered tissues, hyperbaric oxygen therapy (HBO), etc.)
- 4. Management of infection (incision and drainage, empiric and culture directed antibiotics, soft tissue/bone/joint/resection, amputations
- 5. Medical management (hyperglycemia, hypertension, nutritional status, renal status)
- 6. Measures to reduce the risk of ulcer recurrence (regular podiatric care and evaluation; patient preventative education; protective footwear; pressure reduction; surgery to reduce bony prominence/chronic pressure points)
- 7. Surgical management (curative, ablative, elective)
- 8. Multidisciplinary consultation and management

#### Treatment of Diabetic Foot Infections

- 1. Antibiotic therapy in non-limb threatening infection
  - a. Oral agents (amoxicillin/clavulanate, cephalexin, dicloxacillin, clindamycin, levofloxacin
  - b. Parenteral agents (cefazolin, cefotaxime, oxacillin or nafcillin, ampicillin/sulbactam clindamycin
- 2. Antibiotic therapy in limb-threatening infection (ampicillin/sulbactam; ticarcillin/clavulanate; piperacillin/tazobactam; ceftazidime + clindamycin; cefotaxime + clindamycin; fluoroquinolone + clindamycin; vancomycin + levofloxacin + metronidazole)
- 3. Antibiotic therapy in life-threatening infection (ampicillin/sulbactam + aztreonam; piperacillin/tazobactam + vancomycin; vancomycin + metronidazole + ceftazidime; imipenem/cilastatin; fluoroquinolone + vancomycin + metronidazole)

## Management/Treatment of Charcot Foot

- 1. Weightbearing restrictions (crutches, wheelchair)
- 2. Immobilization of foot (splint, cast, removable cast)
- 3. Special footwear or prostheses (orthopedic or molded foot wear, bracing, insoles)
- 4. Patient education for prevention of recurrence
- 5. Surgery

# Prevention of Foot Complications

- 1. Podiatric care
- 2. Protective shoes
- 3. Pressure reduction
- 4. Prophylactic surgery
- 5. Preventive education

## MAJOR OUTCOMES CONSIDERED

• Incidence and morbidity of diabetic foot disorders

- Rates of limb salvage and/or diabetic limb amputations
- Quality of life

#### METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

**COST ANALYSIS** 

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All American College of Foot and Ankle Surgeons Preferred Practice Guidelines are reviewed by the appropriate panel or committee, external reviewers, and approved by the Board of Directors, American College of Foot and Ankle Surgeons.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

## Process of Care

The pedal manifestations of diabetes are well documented and potentially limb-threatening when left untreated. Recognition of potential problems and treatment of foot disorders in a diabetic patient requires the skill of a specialized practitioner to diagnose, manage, treat, and counsel the patient. The integration of knowledge and experience, afforded by a multidisciplinary team, promotes more effective treatment thereby improving outcomes and limiting the risk of lower extremity amputation.

## Diagnosis and Evaluation

The evaluation of the diabetic foot involves careful assimilation of the patient's historical and physical findings and the results of necessary diagnostic procedures. Screening tools may be valuable in patient evaluation and determining levels of risk (see Appendix 1 in the original guideline document).

#### History

A thorough medical and foot history should be obtained from the patient. The following provides guidelines of specific diabetic foot issues that should be addressed:

#### Global History:

- Diabetes disease duration
- Glycemic management/control
- Cardiovascular, renal, and ophthalmic evaluations
- Other comorbidities
- Current treating physicians
- Social habits alcohol/tobacco
- Current medications
- Allergies
- Previous hospitalizations/surgeries

# Foot-Specific History:

- General
- Daily activity
- Footwear
- Chemical exposures
- Callus formation
- Deformities
- Previous foot surgery
- Neuropathy symptoms
- Ischemic symptoms

## Wound/Ulcer History:

- Location
- Duration
- Inciting event or trauma
- Recurrences
- Infections
- Hospitalizations
- Wound care/off-loading methods
- Patient's compliance/wound response
- Interference with wound care/family or social problems for patient
- Previous foot trauma or surgery
- Edema-unilateral versus bilateral
- Previous or active Charcot joint treatment to date

## Physical Examination

Recognizing important risk factors and making a logical, treatment-oriented assessment of the diabetic foot requires a consistent and thorough diagnostic approach using a common language. Without such a method, the practitioner is more likely to overlook vital information and to pay inordinate attention to less critical points in the evaluation. A useful examination will involve identification of key risk factors and assignment into an appropriate foot risk category. Only then can an effective treatment plan be designed and implemented.

## Clinical Examination

All patients with diabetes presenting to any health care practitioner require a pedal inspection and should receive a thorough foot examination at least once each year. Patients with diabetic foot-related complaints will require detailed evaluations more frequently. The examination should be performed systematically so that important aspects are not overlooked. First, one should grossly evaluate the patient and his or her extremities. Any obvious problem can then receive closer scrutiny with examination. For clarity, the key components of the foot examination are presented below in a bulleted format. Each bulleted item represents an important component of the pedal examination or a significant finding to be noted based on evidence which indicates likely predictors for ulceration. It is assumed that a general medical assessment will be determined including measurements of vital signs.

- Palpation of pulses (dorsalis pedis, posterior tibial, popliteal, femoral)
- Subpapillary venous plexus filling time (normal <3 seconds)
- Venous filling time (normal ≤20 seconds)
- Color changes: cyanosis; dependent rubor; erythema
- Presence of edema
- Temperature gradient
- Dermal thermometry
- Integumentary changes consistent with ischemia: skin atrophy;
   nail atrophy; abnormal wrinkling; diminished pedal hair

## **Neurologic Examination**

- Vibration perception: tuning fork 128 cps; measurement of vibration perception threshold (Biothesiometer)
- Light pressure: Semmes-Weinstein 10-gram monofilament
- Light touch: cotton wool
- Two-point discrimination
- Pain: pinprick
- Temperature perception: hot and cold
- Deep tendon reflexes: ankle, knee
- Clonus testing
- Babinski test
- Rhomberg's test

#### Musculoskeletal Examination

- Biomechanical abnormalities: orthopedic deformities (hammertoes, bunion(s) or Tailor's bunion(s), flat or higharched feet, Charcot deformities, iatrogenic deformities (e.g., amputation); limited joint mobility; tendo-Achilles contractures/equinus
- Gait evaluation
- Muscle group strength testing: passive and active, nonweightbearing and weightbearing; foot drop; atrophyintrinsic muscle atrophy
- Plantar pressure assessment: computerized devices; Harris ink mat

## Dermatologic Examination

- Skin appearance: color, texture, turgor, quality; dry skin
- Calluses: discoloration/subcallus hemorrhage
- Fissures (especially posterior heels)
- Nail appearance: onychomycosis, dystrophic; atrophy, hypertrophy; paronychia
- Presence of hair
- Ulceration, gangrene, infection (Note location, size, depth, infection status, etc.)
- Interdigital lesions
- Tinea pedis

 Markers of diabetes: shin spots - diabetic dermopathy; necrobiosis lipoidica diabeticorum; bullosum diabeticorum; granuloma annulare

#### Footwear Examination

- Type of shoe
- Fit
- Shoewear, patterns of wear
- Lining wear
- Foreign bodies
- Insoles, orthoses

## Communicating and Classifying Cumulative Risk

Following a detailed diabetic foot examination, the patient may be classified according to a cumulative risk category. This enables the physician to design a treatment plan which may possibly reduce lower extremity amputations and reduce the patient from a high-risk category to the lowest risk level possible for that patient. Several risk stratification schemes have been proposed, assigning different weights to important risk factors for ulceration including peripheral neuropathy, arterial insufficiency, deformity, high plantar pressures, and prior history of ulceration or amputation. Although no one system has been universally adopted which can predict ulceration, the following simplified risk stratification has been accepted by the International Working Group:

## Risk Categorization System:

- Category = 0; Profile = No neuropathy; Evaluation Frequency = Annual
- Category = 1; Profile = Neuropathy; Evaluation Frequency = Semi-annual
- Category = 2; Profile = Neuropathy, peripheral vascular disease, and/or deformity; Evaluation Frequency = Quarterly
- Category = 3; Profile = Previous ulcer or amputation; Evaluation Frequency = Monthly to quarterly

#### **Diagnostic Procedures**

Diagnostic procedures may be indicated in the assessment and care of the diabetic foot. Consideration should be given to the following tests in concert with members of the consulting team. It should be noted that many of the following tests lack the ability to give a definitive diagnosis and clinical correlation is required.

## **Laboratory Testing**

Clinical laboratory tests that may be necessary in the appropriate clinical situations may include: fasting or random blood glucose, glycohemoglobin (HbA<sub>1</sub>C), complete blood count (CBC) with or without differential, erythrocyte sedimentation rate (ESR), serum chemistries, wound and blood cultures, and

urinalysis. Caution must be exercised in the interpretation of laboratory tests in these patients, since several reports have documented the absence of leukocytosis or fever in the presence of severe foot infections. Frequently, the most prognostic sign of infection severity is recalcitrant hyperglycemia despite normal antihyperglycemic regimes.

## **Imaging Studies**

The diabetic foot may be predisposed to developing both common and unusual infectious or noninfectious processes. This is due in part to the complex nature of the disease and its associated vascular and neuropathic complications. As a result, imaging presentations will vary due to lack of specificity in complex clinical circumstances. This will create a challenge in the interpretation of the imaging studies. Studies should only be conducted to establish or confirm a suspected diagnosis and/or direct patient management.

Plain radiographs should be the initial imaging study in diabetic patients with signs and symptoms of a diabetic foot disorder. X-ray findings in a diabetic foot infection, such as osteomyelitis, may not demonstrate any osseous changes on radiographs for up to 14 days. Plain radiographs may be indicated in the detection of osteomyelitis, osteolysis, fractures, dislocations seen in neuropathic arthropathy, medial arterial calcification, and soft-tissue gas.

Computed tomography (CT) scans may be indicated in the assessment of suspected bone and joint pathology not evident on plain radiographs. This study offers high anatomic detail and resolution of bone with osseous fragmentation and joint subluxation being well visualized.

Technetium bone scans are often used in diabetic foot infections although this modality lacks specificity, especially in the neuropathic patient. Three-phase bone scans may be indicated in the early detection of osseous pathology such as osteomyelitis, fractures, and Charcot arthropathy. However, such imaging tests are best utilized to confirm clinical suspicion and have higher specificity when combined with other scintigraphic techniques such as white blood cell scans.

Gallium 67 citrate is another nuclear medicine technique that is not used as frequently today due to more accurate alternative imaging studies. This study can be used in concert with technetium bone scans to aid in the diagnosis of osteomyelitis and also may be of value in the presence of acute osteoarthropathy.

Indium-111 leukocyte scans,  $Tc_{GG}$ -labeled white-cell scan (HMPO), or other variations of white blood cell scintigraphy are useful in differentiating between osteomyelitis and neuropathic arthropathy due to their relatively high sensitivity and specificity. These tests are expensive and time consuming, but are available at most hospitals when early identification of bone infection is required.

Magnetic resonance imaging (MRI) is often used in evaluating soft-tissue and bone pathologies. This scan may be indicated to aid in the diagnosis of osteomyelitis, deep abscess, septic joint, and tendon rupture. It is a readily available modality which has a very high sensitivity for bone infection and can also be used for surgical planning. Despite its high cost, magnetic resonance imaging

has gained wide acceptance in the management of patients with diabetic foot infections.

#### Vascular Procedures

When the history and physical examination suggest ischemia or the presence of a nonhealing ulcer with absent pedal pulses, further noninvasive testing is warranted. Noninvasive arterial studies (NIAS) should be performed to determine lower extremity perfusion. Such studies may include Doppler segmental arterial pressures, and waveform analysis, ankle-brachial indices (ABI), toe pressures, and transcutaneous oxygen tension (TcPO<sub>2</sub>).

Vascular consultation should be considered in the presence of abnormal noninvasive arterial studies and a nonhealing ulceration. Arteriography with clearly visualized distal runoff allows appropriate assessment for potential revascularization. Digital subtraction angiography (DSA) or magnetic resonance angiography (MRA) are alternatives for evaluation of distal arterial perfusion.

## Neurologic Procedures

Peripheral sensory neuropathy is the major independent risk factor for diabetic foot ulcerations. The patient history and physical examination utilizing the 5.07 Semmes-Weinstein monofilament (10g) wire is sufficient to identify those individuals at risk for ulceration. Vibration perception threshold assessment with the Biothesiometer is also useful in predicting those patients at high risk for ulceration. More sophisticated studies, such as nerve conduction studies, are rarely necessary to diagnose peripheral sensory neuropathy. Patients with neuropathic ulcerations will usually have such profound sensory neuropathy that these studies add little to the management of these patients.

#### Plantar Foot Pressure Assessment

High plantar foot pressures have been identified as a significant risk factor for ulcerations. Measurement of these foot pressures is possible utilizing a variety of modalities. Several computerized systems can provide quantitative measurement of plantar foot pressure. These measurements may be important in identifying areas of the foot at risk for ulceration and possibly in the evaluation of orthotic adjustments. Their primary usage, however, has been in the area of diabetic foot research. The Harris mat, while not as sophisticated, can provide a qualitative measurement of plantar foot pressures and can identify potentially vulnerable areas for ulceration.

# <u>Assessment And Treatment Of Pathologic Entities (Foot Ulcer, Infection, And Charcot)</u>

Effective management of diabetic foot disorders requires knowledge of the potential pathologies, the associated classification systems and the principal tenets of intervention. Ulceration, infection, and Charcot arthropathy, are the most significant of these pathologies and classification systems have been developed for each entity. While the conditions may be seen either as an isolated event or coexisting in the same extremity, each entity is discussed independently.

## Diabetic Foot Ulcer Assessment

## Extremity Assessment

The lower extremity must be assessed for vascular and neuropathic risk factors. The acceptable evaluation parameters are listed in the table titled "Vascular and Neurologic Examination of the Lower Extremity," below. Although positive findings in the neurologic examination rarely require further evaluation, positive findings of vascular insufficiency may require further consultation. The indications for vascular consultation include an ankle brachial index of less than 0.7, toe blood pressure <40 mm Hg or transcutaneous oxygen tension levels of less than 30 mm Hg, since these measures of arterial perfusion are associated with impaired wound healing.

Evaluation Parameters	Normal Values
Vascular:	
Palpation of pulses	Present
Dependent rubor	Absent
Venous filling time	<20 seconds
Capillary refill	<3 seconds
Arterial Doppler exam for ankle-brachial index (ABI)	1.1
Toe pressures	>40 mm Hg
Transcutaneous oxygen tension (TcPO2)	>40 mm Hg
Neurologic:	
Semmes-Weinstein 5.07 monofilament (10 g)	Detected
Biothesiometer (vibration perception threshold)	<25 V
Vibration perception - 128 cps tuning fork	Detected

Present

#### **Ulcer Evaluation**

Description of the ulcer characteristics on presentation is critical for the mapping of its progress during treatment. While some characteristics are more important than others, they all have a prognostic value during management. The presumed etiology of the ulcer needs to be determined (i.e., chemical versus mechanical) as well as ascertaining whether the lesion is neuropathic, ischemic, or neuroischemic in character. The evaluation should include the size and depth of the ulcer, as well as a description of the margins, base, and geographic location on the extremity or foot. All but the most superficial ulcers should be examined with a blunt, sterile probe. The description should note whether or not the sterile probe detects sinus tract formation, undermining of the ulcer margins, or extension of the ulcer into tendon sheaths, bone, or joints. A positive probe to bone finding has a high predictive value for osteomyelitis. The existence of odor or exudates and the character of each should be noted. Cultures may be necessary when signs of inflammation are present. Current recommendations for culture and sensitivity include thorough surgical preparation of the wound site with curettage of the wound base for specimen or with aspiration of abscess material.

#### Classification of Ulcers

Appropriate classification of the foot wound is predicated upon its thorough assessment, should facilitate its treatment, and be generally predictive of expected outcomes. Several systems of ulcer classification are currently in use in this nation and abroad in an attempt to meaningfully describe these lesions and to communicate severity. Perhaps the easiest system is to simply classify the lesions as neuropathic, ischemic, or neuroischemic with descriptors of wound size, depth, and infection. Regardless of which system is ultimately used, the clinician must be able to easily categorize the wound and, once classified, the ensuing treatment should be directed by the underlying severity of pathology. Refer to the original guideline document for descriptions of the following classification systems: Wagner Classification System; Modified Wagner Classification System; University of Texas Wound Classification System.

Imaging studies play an important role in the assessment and evaluation of the diabetic foot ulcer. Plain x-rays are indicated based on the extent and nature of the ulcer. Clinical change in the appearance of the ulcer or failure to heal with appropriate treatment may dictate repeating the radiograph periodically to monitor for osseous involvement. Additional imaging modalities such as nuclear medicine scans, ultrasonography, magnetic resonance imaging, and computed tomography may be indicated predicated on the clinical picture. Recommendations for these modalities are discussed elsewhere.

The section below titled "Assessment Objectives for Foot Ulcerations" summarizes the important elements of the overall assessment of the patient with a diabetic foot ulcer based upon the underlying pathophysiology, possible causal factors, and important predictors of outcome.

## Assessment Objectives for Foot Ulcerations:

- Classification: grade, depth, site, clinical descriptors of wound
- Etiology: mechanical, thermal, chemical trauma
- Neuropathy: vibration perception light touch (10-gram monofilament), deep tendon reflexes
- Vascular: pulses, ankle-brachial index, toe pressures, transcutaneous oxygen tension
- Infection: cultures, radiographs, probe, scans, magnetic resonance imaging
- Deformity/High Pressure: callus, hammertoes, bunion, Charcot, amputation

## Diabetic Foot Ulcers: Treatment

# Goals and General Principles of Treatment

The primary goal in the treatment of diabetic foot ulcers is to obtain wound closure as expeditiously as possible. The resolution of foot ulcers and decreasing the rate of recurrence can lower the probability of lower extremity amputation in the diabetic patient.

The essential therapeutic objectives include:

- Debridement
- Pressure relief (off-loading)
- Appropriate wound management
- Management of infection
- Management of ischemia
- Medical management of comorbidities
- Surgical management

Frequent re-evaluation with response-directed treatment is essential. Once healed, the management consists of decreasing the probability of recurrence.

## Debridement

Debridement of necrotic tissue is an integral component in the treatment of chronic wounds since they will not heal in the presence of nonviable tissue and debris. Adequate debridement must always precede the application of topical wound healing agents, dressings, or wound closure procedures. Types of debridement (autolytic, enzymatic, mechanical, and surgical) are discussed in the guideline document.

Surgical debridement is a key component and a cornerstone in the management of diabetic foot ulcers. Thorough sharp debridement of all nonviable soft tissue and bone from the open wound is accomplished primarily with a scalpel, tissue nippers, and/or curettes. Excision of necrotic tissue extends as deeply and proximally as necessary until healthy, bleeding soft tissue and bone are encountered. Any callus tissue surrounding the ulcer must also be removed. A diabetic ulcer associated with a deep abscess requires hospital admission and immediate incision and drainage. Joint resection or partial amputation of the foot is needed in the presence of osteomyelitis, joint infection, or gangrene. Necrotic

tissue removed on a regular basis can expedite the rate at which a wound heals and has been shown in a recent study to increase the probability of attaining full secondary closure. Less frequent surgical debridement can impact negatively on the rate of wound healing and secondarily increase the risk of infection. Surgical debridement is repeated as often as needed if new necrotic tissue continues to form. Weekly debridement is commonly required.

## Off-loading

Reducing pressure to the diabetic foot ulcer is an essential component of treatment. Without proper off-loading and pressure reduction, ulcers will continually be traumatized to the point that they cannot heal.

The choice of off-loading modality should be determined by the patient's physical characteristics and ability to comply with the treatment, as well as the location and severity of the ulcer. Various centers prefer specific initial modalities, but the clinician frequently must alternate treatments based upon clinical progress of the wound. It is not unusual to practice step-up therapy where increasingly effective modalities are used when little improvement is noted with initial therapy. Some centers prefer to apply total contact casts (TCC) initially and then step-down to less restrictive modalities when lesions have healed or are nearly healed.

The following off-loading techniques have been found to be useful in the management of diabetic foot ulcers:

- Total nonweightbearing: crutches, bed, wheel chair
- Total contact casting
- Foot casts or boots
- Removable walking braces with rocker bottom soles
- Total contact orthoses custom walking braces
- Patellar tendon-bearing braces
- Half shoes or wedge shoes
- Healing sandal surgical shoe with molded plastizote insole
- Accommodative dressings: felt, foam, felted-foam, etc.
- Shoe cutouts (toe box, medial, lateral, or dorsal pressure points)
- Assistive devices: crutches, walker, cane, etc.

It is critically important to remove the patient from the shoes that caused the ulcer. In fact, the consensus of opinion is such that no patient with an active foot ulcer should be placed back into an unmodified shoe until complete healing has occurred.

## Wound Management

Generally, a moist wound environment bandaged to protect it from trauma and local contamination has been shown to facilitate the healing process. The type of dressing selected depends upon such factors as size, depth, location, and the wound surface. Normal sterile saline or fractionalized sterile saline (such as 0.5% normal) are frequently used and are often considered as a standard for wound care. However, there is a conspicuous lack of formal clinical trials to support this practice. Many wound care products are available as viable alternatives to saline-moistened gauze dressings, although few of these agents have been subjected to

comparative trials. These various agents are grouped into different categories and each has its own indications for usage. A brief listing of the dressings and topical agents available, their indications and contraindications are presented in Table 7 of the original guideline document.

The length of time a wound must exist until it is considered chronic is not well defined in the literature. The Wound Healing Society defines a chronic wound as one which has failed to proceed through an orderly and timely repair process to produce anatomic and functional integrity. Skin ulcers, including diabetic foot ulcers, are included in the category of chronic wounds. Recent clinical trials for the treatment of such wounds have used a period of at least 8 weeks during which there have not been signs of active healing or attaining closure. The primary goal in treating the chronic ulcer is to convert it to an acute wound which will then possess the active matrix and cells needed for healing. Reassessment of the entire treatment program is the first step in establishing a new directed approach. The basic principles of treatment discussed for the acute ulcer apply here.

Refer to the original guideline document for discussion of hyperbaric oxygen therapy and other alternative or unproven technologies which are occasionally used in the management of diabetic foot wounds.

## Management of Infection

The presence of infection must be determined and identified as either local (soft tissue or osseous), ascending and/or systemic. Treatment requires early incision and drainage with broad-spectrum empirical antimicrobial therapy. Debridement of all necrotic tissue including bone and joint resection when these structures are involved must also be performed followed by culture-directed antibiotic therapy. In cases involving gangrene or extensive tissue loss, early amputation at the appropriate level should be considered to remove the focus of infection and to attain viable tissue margins. The necessity for culturing and antimicrobial treatment of clinically uninfected wounds is still under investigation. A thorough discussion of the management of infected wounds is presented later in this document (see Diabetic Foot Infections, below).

#### Vascular Insufficiency

Arterial perfusion is a vital component for healing and must be assessed in the ulcerated patient. Vascular reconstructive surgery of the occluded limb improves prognosis and may be required prior to debridement, foot-sparing surgery, and/or partial amputation.

## Management of Comorbidities

Diabetes is a multiorgan system disease, and comorbidities must be assessed and managed via a multidisciplinary team approach for optimal outcomes. Patient compliance has been identified as a significant factor in the expected prognosis and the prevalence of both ulceration and limb loss.

## Surgical Management

Refer to the original guideline document for discussion on curative, ablative, and elective surgical interventions.

The basic guidelines or tenets for the management of diabetic foot ulcers are summarized below:

- Debridement of necrotic tissue: surgical mechanical, autolytic, enzymatic
- Pressure reduction: crutches, healing sandal, contact cast, walking brace, foot cast, felt aperture padding, etc.
- Wound care: topical saline gauze dressings, antiseptics, special dressings, growth factors (becaplermin), bioengineered tissues, hyperbaric oxygen, etc.
- Infection: incision and drainage, empiric and culture directed antibiotics, soft tissue/bone/joint resection, amputations
- Vascular: pedal or proximal bypass, endovascular procedures
- Medical management: hyperglycemia, hypertension, nutritional status, renal status
- Reduce the risk of recurrence:
  - Regular podiatric care and evaluation
  - Patient preventative education
  - Protective footwear
  - Pressure reduction
  - Surgery to reduce bony prominence/chronic pressure points

## Preventing Ulcer Recurrence

Prevention is considered a key element in avoiding ulcer recidivism and diabetic lower extremity amputation. This is best accomplished with a multidisciplinary approach consisting of a team of dedicated professionals committed to this ideal. Typical team members might include the following specialists: podiatrist or podiatric surgeon, internist, endocrinologist, infectious disease physician, cardiologist, nephrologist, neurologist, vascular surgeon, orthopedic surgeon, teaching nurse, and pedorthist (see Figure 2 in the original guideline document). Patient education assumes a primary role in this scheme and encompasses instruction in foot hygiene, the need for daily inspection, proper footwear, and the necessity for prompt treatment of new lesions. Regular podiatric visits, including debridement of calluses and ingrown toenails, provide an opportunity to reinforce appropriate self-care behavior as well as allowing early detection of new or impending foot problems. Therapeutic shoes with pressure-relieving insoles and high toe box which protect the high-risk foot are an essential element of the prevention program and have been associated with significant reductions in ulcer development. Walking/athletic style footwear or commercially available orthopedic shoes can be accommodated with various types of foot orthoses to effectively relieve high plantar pressures. Custom-molded shoes are sometimes necessary for severely deformed feet which cannot be adequately protected by standard footwear.

Prophylactic or elective surgical correction of structural deformities that cannot be accommodated by therapeutic footwear in the carefully selected patient, serve to reduce high-pressure areas and ultimately prevent ulcer recurrence. Many of the procedures previously mentioned in the discussion on curative surgery would also be indicated in the elective reconstruction of the nonulcerated foot. Common operations performed in this regard include the correction of hammertoes,

bunions, and various exostoses of the foot. Tendo-Achilles lengthening procedures are often performed as ancillary procedures to reduce forefoot pressures which contribute to recurrent ulcerations. Since patients with healed ulcers are at high risk for future ulceration, these prevention efforts must be incorporated into a lifelong surveillance and treatment program. A Practice Pathway (algorithm) which summarizes the important parameters for both assessment and treatment of foot ulcers is illustrated in the original guideline document.

#### Diabetic Foot Infections

Diabetic foot infections may be categorized into non-limb-threatening or limb-threatening infections (see original guideline document for details). Non-limb-threatening infections can usually be managed on an outpatient basis with close supervision from the practitioner. For limb-threatening infections, hospitalization is required in order to treat the infection as well as the systemic sequelae. Patients with poor vascular status and ischemia have an increased potential for limb amputation and require prompt consultation for potential revascularization.

## Assessment of Diabetic Foot Infections

When evaluating the patient, a problem-directed history and physical examination should be obtained. A systematic approach to the complete assessment of these patients is required since there is evidence that they are often inadequately evaluated even when hospitalized. The past medical history should assess the neurologic, cardiovascular, renal, and dermatological status of the diabetic patient. Medications that the patient is currently taking, as well as prior antibiotic use, may interfere with planned treatments or indicate that standard treatments are likely to be ineffective. Pain should be considered an unreliable symptom in persons with peripheral neuropathy. The patient should be questioned regarding previous ulcerations, infections trauma, and surgeries at the present site or any other past location of infection. Constitutional symptoms such as nausea, malaise, fatique, vomiting, fever, or chills are important clinical clues when presented with an infected diabetic foot. Severe infection or sepsis may be present and must be considered. In approximately 50% of diabetic patients presenting with significant infection, however, systemic signs (fever and leukocytosis) are absent. Frequently, the only indication of infection is unexplained or recalcitrant hyperglycemia. Laboratory testing might include complete blood count with or without differential, blood cultures, glycosylated hemoglobin, fasting blood sugar, sedimentation rate, and urinalysis. Other tests should be performed as indicated by the patient's condition or comorbidities.

The history of the wound or infection should include the onset, duration, and appearance before infection of the area. Depth or size of the ulcer, amount of drainage, swelling, color, odor, and extent of infection should be evaluated. The infection or ulcer should be probed to determine the presence of bone or joint involvement, sinus tracts, or extension into tendon sheaths. The latter are common routes for the spread of infection both distally and proximally. If bone is exposed it is assumed that the patient has osteomyelitis until proven otherwise. Both anaerobic and aerobic cultures should be obtained from pus or curettage of the ulcer base, since studies have shown good concordance with the true pathogen. For patients with clinically uninfected or noninflamed neuropathic ulcers, the role of antibiotic therapy is still in question. In these instances,

therefore, wound culture is most likely unnecessary. If osteomyelitis is suspected, bone cultures are necessary to make the definitive diagnosis as well as to isolate the true pathogen. However, this must be balanced against the possibility of contaminating noninfected bone in the presence of an active soft-tissue infection.

Imaging studies are helpful in the overall assessment of diabetic foot infections, notwithstanding their shortcomings. Plain-film x-rays may indicate the presence of bony erosions and/or gas in the soft-tissues. It is important to note that the demonstration of osteomyelitis by plain radiographs lags the onset of bone involvement by 10 to 14 days. Radionuclide bone scans such as technetium-99 (Tc99) may demonstrate abnormal uptake of the radionuclide before changes are visible on radiographs. This finding may be less specific in patients with peripheral neuropathy or with any pre-existing osseous condition that causes increased bone turnover (e.g., surgery, fracture, neuropathic arthropathy). A combination of scans such as the technetium-99m and an indium-labeled leukocyte scan, or the technetium-99m-hexamethylpropyleneamine oxime (Tc99m-HMPAO)-labeled leukocyte scan may aid in differentiating between Charcot arthropathy and osteomyelitis with greater accuracy. Magnetic resonance imaging has generally supplanted the computed tomography scan in the early diagnosis of osteomyelitis due to its higher tissue contrast and ability to detect both soft-tissue and marrow inflammation. Magnetic resonance imaging can also be used to follow the resolution of infection or as an aid in surgical planning. None of the aforementioned imaging modalities are 100% sensitive and specific for diagnosing or ruling out the presence of bone infection. Furthermore, these tests may not be readily available and are quite expensive. Appropriate clinical assessment and diagnostic acumen should therefore remain the guiding principles to management.

Potential items for initial patient evaluation on hospital admission include the following:

- History and physical
- Radiographs
- Vascular testing
- Possible consultations medicine/endocrine, infectious disease, vascular surgery, orthopedic surgery, nutrition
- Cultures reliable wound cultures, blood cultures
- Labs complete blood count with differential, sedimentation rate, glucose, others

## Treatment of Diabetic Foot Infections

Diabetic foot infections should be managed with a multidisciplinary team approach. This should include obtaining the appropriate consultations as well as admitting the patient to a hospital setting in emergent cases or when the patient does not respond to a course of outpatient treatment. Hospitalization of limb-threatening infections should be considered mandatory. Diabetic foot infections, whether non-limb-threatening or limb-threatening, need to be monitored very closely. Equally important, especially in the outpatient management of foot infections, patient compliance and education must be addressed in order to provide the best possible outcome.

Non-Limb-Threatening Infections

Non-limb-threatening infections complicating foot ulcers may be initially treated in an outpatient setting. Many of these mild or moderate infections are monomicrobial, with Staphylococcus aureus, Staphylococcus epidermidis, and streptococci being the most common infection organisms. Cultures should be taken from a curettage of the ulcer base to obtain a reliable specimen. Antibiotic therapy should be initiated as soon as possible with an agent providing adequate gram-positive coverage, recognizing that gram-negative organisms might also be involved (see the section below titled "Empirical Antibiotic Therapy: Non-limbthreatening Infection"). Antibiotic therapy should be adjusted according to culture results and the patient's response to treatment. The wound should be assessed and cleansed thoroughly, using proper debridement as indicated. Of the several topical agents that can be used on the infected wound, no one agent or topical antibiotic has been proven superior. The wound itself should be managed according to principles discussed under the section titled "Wound Management," above. Most importantly, the patient should be reassessed within 48 to 72 hours. If no improvement is noted, hospitalization with intravenous antibiotics should be considered. Management of this type of infection should also include close monitoring of the patient's hyperglycemia and general health status. Patient compliance as well as a reduction in the pressure of the infected limb must be considered early on in the treatment of any diabetic foot infection.

Empirical Antibiotic Therapy: Non-limb-threatening Infection:

## Oral Agents:

- Amoxicillin/Clavulanate
- Cephalexin
- Dicloxacillin
- Clindamycin
- Levofloxacin

## Parenteral Agents

- Cefazolin
- Cefotaxime
- Oxacillin or Nafcillin
- Ampicillin/Sulbactam
- Clindamycin

# Threatening Infections

Limb-threatening infections may have life-threatening complications, especially when left untreated. Due to immunosuppression from diabetes, up to 50% of these patients may present with no systemic symptoms or leukocytosis. Other patients, however, do present with evidence of systemic toxicity including fever, chills, loss of appetite, and malaise. Such findings in diabetic patients should alert the clinician to the potential severity of infection. Often present is an uncontrollable hyperglycemia, despite routine therapy and a loss of appetite.

Limb-threatening infections have one or more of the following findings: greater than 2 cm of cellulitis, lymphangiitis, soft-tissue necrosis, fluctuance, odor,

gangrene, and/or osteomyelitis. When such an infection is recognized, the patient requires emergent hospital admission for appropriate intervention. Upon admission, the patient requires a complete history and physical examination. The patient's cardiovascular, renal, and neurologic risks should be evaluated to assess for secondary complications of diabetes and associated comorbidities. The foot requires a through evaluation to assess clinical extent of the infectious process. Vascular status must be assessed to ensure adequate arterial inflow is present. Ulceration, if present, must be probed for bone or joint involvement and subcutaneous sinus tracts, while also measuring the size and depth. Radiographs should be taken and evaluated for evidence of osteomyelitis or soft-tissue gas. If gas is identified in the ankle or hindfoot, radiographs of the lower leg should be obtained to assess the extent of the gas formation. Deep, reliable aerobic and anaerobic cultures should be obtained in the presence of high fever since such clinical finding a re often indicative of septicemia. Other appropriate laboratory studies, including complete blood count with differential and sedimentation rate, should be obtained as appropriate. Glucose management must be initiated to optimize metabolic perturbations and to improve leukocyte function. The patients' nutritional and metabolic status must be assessed and properly maintained since such relatively common impairments in these patients can have adverse effects on wound healing and resolution of infection.

Consultations are typically required in the management of these complex patients, and are indicated for risk assessment and medical management. Medical, endocrinology, cardiology, nephrology, and diabetic teaching nurse consultations are often routinely necessary to optimize patient care and for full assessment of surgical risks. Infectious disease and vascular surgery consultations are obtained when complex infections or significant ischemia are identified. A multidisciplinary approach to managing these patients has been shown to significantly improve outcomes.

Early surgical treatment of the affected site is typically necessary as an integral part of infection management. This may include simple debridement of the soft tissues, wide incision and drainage of the pedal compartments, or open amputation to eliminate extensive areas of infection. Aerobic and anaerobic tissue cultures should be obtained at the time of debridement, and should be obtained from the depth of the wound to provide reliability. Although many initial drainage procedures can be done at the bedside for neuropathic patients, most will require thorough debridement in the operating room. Anesthesia may include local, regional, or general anesthetics. Spinal blocks are typically avoided in patients who may be septic. Even the sickest of patients should be considered for emergent incision, drainage, and debridement procedures since their illness is directly attributable to the severity of their infection. Life-threatening infections necessitate immediate surgical attention and such procedures should not be delayed while waiting for radiological or medical workup of other comorbid conditions.

Polymicrobial infection should be anticipated, with a variety of gram-positive cocci, gram-negative rods, and anaerobic organism predominating (see Table 11 in the original guideline document). Empirical antibiotic therapy typically includes broad-spectrum coverage for more common isolates from each of these three categories (see the section titled "Empirical Antibiotic Therapy; Limb-or life-threatening Infection," below). Fully comprehensive empiric coverage is usually

unnecessary unless the infection is life-threatening. Hospital therapies are usually initiated with intravenous medications, although most fluoroquinolones can be administered orally in conjunction with other parenteral therapy. Once wound culture results have been obtained, the initial antimicrobial therapy may require adjustment to provide more specific coverage or to provide therapy against resistant organisms that are causing persisting infection. Recent evidence also supports the efficacy of initial parenteral therapy followed by the appropriate oral agent. If the patient develops evidence of recurrent infection while under antibiotic therapy, repeat cultures should be obtained to assess for superinfection. Methicillin-resistant staphylococci have been emerging as important pathogens in chronically treated diabetic foot ulcer patients. These organisms must be detected early and treated appropriately to avoid further tissue loss or extension of infection.

Empirical Antibiotic Therapy; Limb-or life-threatening Infection

## Limb-Threatening:

- Ampicillin/Sulbactam
- Ticarcillin/Clavulanate
- Piperacillin/Tazobactam
- Ceftazidime + Clindamycin
- Cefotaxime+ Clindamycin
- Fluoroquinolone + Clindamycin
- Vancomycin + Levofloxacin + Metronidazole

## Life-Threatening:

- Ampicillin/Sulbactam + Aztreonam
- Piperacillin/Tazobactam + Vancomycin
- Vancomycin + Metronidazole + Ceftazidime
- Imipenem/Cilastatin
- Fluoroquinolone + Vancomycin + Metronidazole

The surgical wound may require repeated surgical debridements to completely eradicate infection and soft-tissue necrosis. Wound care is initiated on the first or 2nd postoperative day and may initially involve saline gauze dressing changes. Other dressings may be utilized to aid with healing and are listed elsewhere. If the wound fails to progress, the patient's vascularity, nutrition, infection control, and wound off-loading must be re-evaluated.

Once soft-tissue infection is under control and management of any osseous infection has been initiated, consideration may be given to wound closure or definitive amputation. Restoration and maintenance of function and independence is the ultimate goal for the patient. The residual extremity requires close follow-up, regular diabetic foot exams, periodic foot care, and appropriate footwear therapy.

Osteomyelitis and joint infection, when identified by clinical assessment or imaging studies, will require excision of bone for microbiological and histopathological evaluation. If the patient's soft-tissue infection is controlled,

consideration may be given to stopping antibiotic therapy 24-48 hours preoperatively to improve culture accuracy. Both studies should have positive findings including necrosis, chronic inflammatory infiltrates, and positive isolation of bacteria to diagnose osteomyelitis. Resection of infected bone with or without local amputation and concurrent antimicrobial therapy is the optimal management for osteomyelitis. If the affected bone has been completely resected or amputated, the infection may be treated as a soft-tissue infection. However, if residual bone is present in the wound, the patient will likely require 48 weeks of antibiotic therapy based on the culture results. Intravenous or oral agents may be used depending on the microbial isolates and the infection severity. Antibioticimpregnated bone cement has been advocated for treatment of osteomyelitis but should be utilized if the bone has been thoroughly debrided and the soft-tissue envelope is adequate for wound closure after antibiotic-impregnated bead placement. Typically, gentamycin, tobramycin, or vancomycin are the agents used in the beads. It is generally recommended that the antibiotic beads be removed 2 weeks or so after placement.

A Practice Pathway (algorithm), contained within the original guideline document, presents a comprehensive overview to the diagnosis and management of diabetic foot infections.

## Charcot Foot (Neuropathic Osteoarthropathy)

Refer to the original guideline document for definition, etiology, and classification of Charcot Arthropathy.

Clinical Diagnosis of Acute Charcot Neuropathic Osteoarthropathy

The initial diagnosis of acute Charcot arthropathy is often clinical, based on profound unilateral swelling, increased skin temperature, erythema, joint effusion, and bone resorption in an insensate foot. These characteristics, in the presence of intact skin, are often pathognomonic of acute Charcot arthropathy. In more than 75% of cases, the patient will present with some degree of pain in an otherwise insensate extremity. The diagnosis is complicated by the fact that in some cases, patients first present with a concomitant ulceration which raises questions of potential contiguous osteomyelitis. When faced with a warm, edematous, erythematous, insensate foot, plain radiographs are invaluable in ascertaining the presence of osteoarthropathy. In most cases, no further imaging studies will be required to make the correct diagnosis. With a concomitant wound, it may initially be difficult to differentiate between acute Charcot arthropathy and osteomyelitis solely based on plain radiographs. Additional laboratory studies may prove useful in arriving at a correct diagnosis. The white blood cell count (WBC) with a left shift will often be elevated in acute osteomyelitis, although this can be blunted in persons with diabetes. While the erythrocyte sedimentation rate may also be elevated in the case of acute infection, it often responds similarly to any inflammatory process and is therefore nonspecific. As in the case with any ulcer, it should be probed to ascertain penetration to bone. A bone biopsy, when indicated, should be considered as the most specific method of distinguishing between osteomyelitis and osteoarthropathy in these circumstances. A biopsy consisting of multiple shards of bone and soft tissue embedded in the deep layers of synovium is pathognomonic for neuropathic osteoarthropathy. Technetium bone scans are relatively expensive and generally nonspecific in assisting in the differentiation

between osteomyelitis and acute Charcot arthropathy. Indium scanning, while still expensive, has been shown to be more specific. Additional studies utilized in differentiating Charcot arthropathy from osteomyelitis include bone scans utilizing white blood cells labeled with Tc-HMPAO and magnetic resonance imaging.

## Management of Acute Charcot Neuropathic Osteoarthropathy

Immobilization and reduction of stress are the mainstays of treatment for acute Charcot arthropathy. Many investigators advocate complete nonweightbearing through the use of crutches or other assistive modalities during the initial acute period. While this is an accepted form of treatment, three-point gait may, in fact, increase pressure to the contralateral limb, thereby predisposing it to repetitive stress and ulceration or neuropathic fracture. Following a period of off-loading, a reduction in skin temperature and edema indicates the stage of guiescence at which point the patient progresses into the post-acute phase of treatment. Progression to protected weightbearing is permitted, usually with the aid of some type of assistive device. Through the use of appropriately applied total contact casts or other off-loading modalities (e.g., fixed ankle, walker, bivalved casts, total contact prosthetic walkers, patellar tendon-bearing braces, etc.), most patients may safely ambulate while bony consolidation of fractures progresses. The mean time of rest and immobilization (casting followed by removable cast walker) prior to return to permanent footwear is approximately 4-6 months. There is recent interest in the adjunctive use of bisphosphonate therapy in acute Charcot arthropathy to help expedite the conversion of the acute process to the quiescent, reparative stage. Similarly, there is interest in managing acute cases with ancillary bone growth stimulation to promote rapid consolidation of fractures. Although promising in theory, neither of these adjunctive treatment to date have been conclusively proven effective through large prospective, randomized clinical trials.

Reconstructive surgery may be considered if a deformity or instability exists that cannot effectively be controlled or accommodated by prescription footwear or bracing. If the arthropathy is identified in its early stages and nonweightbearing is instituted, surgery is usually unnecessary. The consensus of opinion is such that surgery in the acute stage is generally not advisable due to the extreme hyperemia, osteopenia, and edema present. Surgical intervention during the acute phase, however, may be considered in the presence of acute subluxation without osteochondral fragmentation. Refer to the guideline document for further discussion of reconstructive surgery.

The goal of any surgery undertaken on the Charcot foot is to create a stable, plantigrade foot that may be appropriately accommodated. Surgery is generally undertaken only after radiographic, dermal thermometric and clinical signs of quiescence.

Following surgery, patients are immobilized until skin temperatures and postoperative edema normalize. As with those treated nonsurgically, following prolonged cast immobilization patients progress to a removable cast walker followed by permanent prescription footwear. Mean times from operation to the wearing of therapeutic shoes have been reported in the range of 27 weeks (7 months). Careful patient selection and management is the rule with these

complex diabetic patients since amputation can be an unwanted complication of failed surgical procedures.

Figure 7 in the original guideline document illustrates a suggested Practice Pathway (algorithm) for the assessment and management of diabetic neuropathic osteoarthropathy.

## Surgical Protocols

Refer to the original guideline document for discussion of surgical protocols, including site of surgery, preoperative laboratory testing, anesthesia, prophylactic antibiotics, and hemostasis.

## <u>Prevention</u>

Below are listed the important attributes of a diabetic foot prevention program undertaken within the framework of the multidisciplinary team. Refer to the original guideline document for narrative discussion on prevention.

- 1. Podiatric Care
  - Regular visits, examinations, and footcare
  - Risk assessment
  - Early detection and aggressive treatment of new lesions
- 2. Protective Shoes
  - Adequate room to protect from injury; well cushioned walking sneakers, extra depth, custom-molded shoes
  - special modifications as necessary.
- 3. Pressure Reduction
  - Cushioned insoles, custom orthoses, padded hosiery
  - pressure measurements computerized or Harris mat
- 4. Prophylactic Surgery
  - Correct structural deformities hammertoes, bunions, Charcot
  - Prevent recurrent ulcers over deformities
  - Intervene at opportune time
- 5. Preventive Education
  - Patient education need for daily inspection and necessity for early intervention
  - Physician education significance of foot lesions, importance of regular foot examination, and current concepts of diabetic foot management

## CLINICAL ALGORITHM(S)

Algorithms are provided for:

- Diabetic Foot Disorders Ulcer: A Clinical Practice Pathway
- Diabetic Foot Disorders Infection: A Clinical Practice Pathway;
- Diabetic Foot Disorders Charcot Foot: A Clinical Practice Pathway

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Diabetic foot complications can be dramatically reduced through appropriate management and prevention programs. The multidisciplinary team approach to diabetic foot disorders has been demonstrated as the optimal method to achieve favorable rates of limb salvage in the high risk diabetic patient. Foot care programs emphasizing preventive management can reduce the incidence of foot ulceration through modification of self care practices, appropriate evaluation of risk factors, and the formulation of treatment protocols aimed at early intervention, limb preservation, and the prevention of new lesions. The goal of a 40-50% reduction in diabetic limb amputations is certainly attainable if these concepts are embraced and incorporated into daily patient care.

A growing body of evidence suggests that toe blood pressures may have a role in predicting those diabetic patients at risk for foot ulceration as well as in the prediction of successful wound healing. Transcutaneous oxygen tension measurements have received similar support in the literature. Although not consistently predictive of wound healing outcomes, these physiologic measures of tissue oxygenation are highly predictive of wound healing failure at levels below 25 mm Hg. Both of these tests can be performed distally on the foot, regardless of arterial calcification in the major pedal arteries, and are favorable at pressures in the range of 40 mm Hg.

Laser Doppler velocimetry and measurement of skin perfusion pressure (SPP) with this modality has been used primarily in research settings, but can accurately assess blood flow velocity in the superficial arterioles and capillaries of the skin. Several recent reports indicate that laser Doppler measurement of skin perfusion pressure can be highly predictive of critical limb ischemia and wound healing failure at levels less than 30 mm Hg.

Necrotic tissue removed on a regular basis can expedite the rate at which a wound heals and has been shown in a recent study to increase the probability of attaining full secondary closure.

### POTENTIAL HARMS

Although not specifically discussed in the guideline, medications pose risk of side effects and adverse reactions. In addition, surgical procedures pose risk of complications.

As a diagnostic vascular procedure, ankle-brachial indices may be misleading since ankle pressures can be falsely elevated due to medial arterial calcinosis and noncompressibility of affected arteries.

#### CONTRAINDICATIONS

#### **CONTRAINDICATIONS**

A list of contraindications to specific types of dressings and topical therapies/agents used in wound management can be found in Table 7 of the original guideline document.

## QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

These guidelines are intended to provide evidence-based guidance for general patterns of practice and not to necessarily dictate the care of a particular patient. Although the intent of the guideline developers is to be as comprehensive as possible, they realize that the work is, in fact, a work in progress and will require future modification as new knowledge becomes available.

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

# BIBLIOGRAPHIC SOURCE(S)

Frykberg RG, Armstrong DG, Giurini J, Edwards A, Kravette M, Kravitz S, Ross C, Stavosky J, Stuck R, Vanore J. Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Surgeons. J Foot Ankle Surg 2000; 39(5 Suppl): S1-60. [248 references]

**ADAPTATION** 

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

2000 Sep

#### GUI DELI NE DEVELOPER(S)

American College of Foot and Ankle Orthopedics and Medicine - Professional Association

American College of Foot and Ankle Surgeons - Medical Specialty Society

#### GUI DELI NE DEVELOPER COMMENT

This practice guideline is based upon current practice and extensive reviews of the clinical literature and has been developed in cooperation with the American College of Foot and Ankle Orthopedics and Medicine (ACFAOM) by the Clinical Practice Core Committee and the Diabetes Committee of the American College of Foot and Ankle Surgeons (ACFAS).

## SOURCE(S) OF FUNDING

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## **GUI DELI NE COMMITTEE**

The Clinical Practice Core Committee of the American College of Foot and Ankle Surgeons (ACFAS)

The Diabetes Committee of the American College of Foot and Ankle Surgeons (ACFAS) and American College of Foot and Ankle Orthopedics and Medicine (ACFAOM).

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

An update is not in progress at this time.

#### GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Foot and Ankle Surgeons (ACFAS) Web site.

Print copies: Available from the American College of Foot and Ankle Surgeons, 515 Busse Highway, Park Ridge, IL 60068-3150; Web site: <a href="https://www.acfas.org">www.acfas.org</a>.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Diabetic foot disorders. A quick reference guide. Park Ridge (IL): American College of Foot and Ankle Surgeons, 2000. 15 p.
- Diabetic foot disorders ULCER: A laminated clinical practice pathway treatment algorithm. Park Ridge (IL): American College of Foot and Ankle Surgeons, 2000.
- Diabetic foot disorders INFECTION: A laminated clinical practice pathway treatment algorithm. Park Ridge (IL): American College of Foot and Ankle Surgeons, 2000.
- Diabetic foot disorders CHARCOT FOOT: A laminated clinical practice pathway treatment algorithm. Park Ridge (IL): American College of Foot and Ankle Surgeons, 2000.

Print copies: Available from the American College of Foot and Ankle Surgeons, 515 Busse Highway, Park Ridge, IL 60068-3150; Web site: <a href="https://www.acfas.org">www.acfas.org</a>.

## PATIENT RESOURCES

The following is available:

• Diabetic foot problems and treatments (patient brochure). Park Ridge (IL): American College of Foot and Ankle Surgeons, 2001.

Electronic copies: Available from the <u>American College of Foot and Ankle Surgeons (ACFAS) Web site</u>.

Print copies: Available from the American College of Foot and Ankle Surgeons, 515 Busse Highway, Park Ridge, IL 60068-3150; Web site: <a href="www.acfas.org">www.acfas.org</a>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### NGC STATUS

This NGC summary was completed by ECRI on October 31, 2001. It was reviewed by the guideline developers as of March 11, 2002.

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